

# **EXHIBIT B**

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- Defendants implemented employment evaluation policies and performance metrics that impeded their pharmacists' efforts to comply with laws and regulations and meet standards of care.
- Defendants' local stores filled thousands of prescriptions presenting red flags without evidence of resolving those red flags.
- Defendants and their pharmacists have a corresponding responsibility to only fill prescriptions for controlled substances that are issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his/her professional practice.
- Defendants' performance metrics and pharmacy operations financial incentives hampered the ability of pharmacists employed by the Chain Pharmacies to maintain effective controls to guard against the diversion of controlled substances through Defendants' pharmacies.
- Defendants failed to provide their pharmacists with data, information and the tools necessary to assist their pharmacists in fulfilling their corresponding responsibility duties, including but not limited to, utilizing dispensing data to identify patterns, trends, and practitioners possibly involved in diversion as well to recognize and resolve red flags. The subsequent result of the failure to provide such data, information, and tools was the diversion of significant quantities of controlled substances, particularly opioids, outside of the closed distribution and dispensing system for controlled substances.

I offer my opinions herein to a reasonable degree of professional certainty. Based on the totality of the circumstances, it is my opinion that the Defendants failed to maintain effective controls to guard against diversion. My opinion is based upon the review of Defendants' policies, procedures and practices as well as the dispensing data that each defendant provided and which demonstrated that Defendants' dispensed thousands of controlled substances in the presence of known red flags. The dispensing of prescriptions without the resolution of obvious and known red flags did not meet the required pharmacy practice and regulatory standards for dispensing controlled substances resulting in a widespread failure to maintain effective controls to guard against the diversion of controlled substances. I reserve the right to supplement this report if new information becomes available.

**Introduction**

The opinions presented are based on my experience and expertise in the practice and regulation of pharmacy. From 1988 to 2020, I served as the Executive Director and the CEO of the National Association of Boards of Pharmacy (NABP). NABP was established as an impartial organization in 1904. The members of NABP are the state agencies that regulate the practice of pharmacy. NABP supports the state boards of pharmacy by developing, implementing, and enforcing uniform standards for the purpose of protecting the public health. NABP also helps state boards of pharmacy protect public health and safety through its pharmacist license transfer, pharmacist competence assessment, and accreditation programs. As Executive Director I oversaw the day-to-

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What follows is a list and description of certain red flags of diversion and the number of times that each red flag appeared in Defendants dispensing data from their pharmacies in Lake and Trumbull counties.

Red Flags of diversion can generally be categorized Prescriber Red Flags, Patient Red Flags, Prescription Red Flags and Pharmacy Red flags.

Defendants in this action have produced dispensing data from the pharmacies they operated in Lake and Trumbull counties Ohio. A number of Red Flags can be identified using the dispensing data. I have relied upon SLCG and Craig McCann to review and calculate the number of prescriptions dispensed, the amount of dosage units dispensed, and the morphine milligram equivalents dispensed for each red flag by pharmacy chain that I have identified below. These summaries can be found in Dr. McCann's report as red flags 1-16 ("Red Flag Computations").

1. Patients traveling long distances to fill opioid prescriptions –
  - a. Pharmacy Distance- Patient generally travels over 25 miles to pharmacy.
  - b. Prescriber Distance- Patient generally travels over 25 miles to prescriber.

In the usual and customary practice of pharmacy, patients ordinarily frequent pharmacies that are convenient to their lifestyles. That convenience translates into using a pharmacy that is close to their residence or place of employment. Exceptions can occur when the individual's drug coverage under their insurance plan mandates certain pharmacies, the pharmacy that they frequent is out of a medication, or the patient is being treated by practitioners at a tertiary care facility that is highly specialized to provide services such areas as cardiac surgery, cancer treatment and management, burn treatment, plastic surgery, neurosurgery and other complicated treatments or procedures. From the data reviewed, these exceptions did not appear to be factors impacting the data. Further, according to the CDC, nearly nine out of ten Americans live within five miles of a community pharmacy.<sup>43</sup> An earlier study stated that "more than 90% of Americans live within 2-miles to one of these pharmacies."<sup>44</sup> A patient that travels an inordinate distance (greater than 25 miles) to a particular pharmacy to obtain controlled substances is a recognized red flag that should be known to a pharmacist.<sup>45</sup> The use of 25 miles as a reference point is based upon standards used by states

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<sup>43</sup> CDC, Get to Know Your Pharmacist, <https://www.cdc.gov/heartdisease/pharmacist.htm>.

<sup>44</sup> Dima Qato, Shannon Zenk, Jocelyn Wilder, Rachel Harrington, Darrell Gaskin, & G. Caleb Alexander, *The availability of pharmacies in the United States: 2007–2015*, PLoS One 2017;12(8), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5559230/#pone.0183172.ref002>.

<sup>45</sup> In the *Holiday CVS* administrative action, a patient travelling a long distance to fill prescriptions was noted as a red flag and "indicator of possible diversion"). In *Pharmacy Doctors Enterprises, Inc., v. Drug Enft Admin.*, 789 Fed. Appx. 724, 730 (11th Cir. 2019), customers traveling "hundreds of miles

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Iowa and North Carolina Boards of Pharmacy also examined the impact of the pharmacist workplace on patient care and medication errors. Most recently, the Ohio and California Boards of Pharmacy conducted and decided to conduct, respectively, surveys of pharmacists licensed by their boards. The Ohio Board of Pharmacy noted in its survey that, “Capturing this data is important as pharmacist working conditions have been identified as a concern among licensees, state regulators (several of which have issued similar surveys) and national organizations.”<sup>447</sup>

The Defendants also tie pharmacist bonuses and other financial incentives to the number of prescriptions filled, including prescriptions for controlled substances. The added direct impact on salary and bonus if metrics were not met further overrode pharmacists’ professional judgment and legal responsibilities.

In 2013, the DEA expressed concerns that bonus incentives for dispensing controlled substances could “lead to bad pharmacist decisions because they know they get will something out of filling scripts.”<sup>448</sup> Walmart “agree[d]” with the DEA’s concerns “that there should be no special incentives for filling controlled substance prescriptions” but then does not appear to have excluded controlled substance prescriptions from bonus calculation formulas.<sup>449</sup>

**K. Summary**

This opinion is based upon my review of information, data, and considerations presented for my review, experience and expertise in the practice and regulation of pharmacy, and the usual and customary practice of pharmacy and pharmacy practices. It is my opinion that the Defendants and their pharmacists held, and continue to hold, a corresponding responsibility to only fill prescriptions for controlled substances that are issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his/her professional practice. Based on my review of the policies and procedures instituted by the Defendants governing pharmacy operations, Defendants’ pharmacists abilities to carry out their corresponding responsibility obligations were significantly impacted. Further, Defendants failed to provide their pharmacists with the data and tools necessary to fulfill their corresponding responsibility duties, including but not limited to, providing their pharmacists with access to dispensing data as well as the analysis of that data as it relates to red flags of diversion. The failure to provide such data resulted in significant quantities

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<sup>447</sup> State of Ohio, Board of Pharmacy, Pharmacist Workload Survey, April 2021.

<https://www.aacp.org/article/2019-national-pharmacist-workforce-study>

<sup>448</sup> WMT\_MDL\_000233226 (NACDS DEA Compliance Working Group Meeting Summary (Feb. 12, 2013).

<sup>449</sup> WMT\_MDL\_000361054 - WMT\_MDL\_000361069; WMT\_MDL\_000891159.